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PATENT SPECIFICATION 984,149

DRAWINGS ATTACHED.

984,149

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Int. Cl.:—B 67 b /A 61 m.

COMPLETE SPECIFICATION.

Self Sealing Pierceable Stopper for Sealed Containers.

We, BECTON, DICKINSON AND COMPANY, a corporation organised and existing under the laws of the State of New Jersey, United States of America, of Rutherford, New Jersey, United States of America, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to self sealing pierceable stoppers for sealing containers.

In medical, biological and laboratory techniques, sealed containers are frequently provided with pierceable self sealing stoppers whereby entry can be made into the container by means of a hypodermic needle so that fluids can be inserted into and removed from the container without breaking the sterility of the container. After the needle is removed from the stopper it immediately reseals. One type of stopper used for this purpose is made of resilient material and is provided with a cylindrical plug portion, an enlarged head portion and a pierceable diaphragm extending across the stopper. Stoppers of this type have frequently been used with evacuated tubes and containers used in the collection of blood. This type of stopper has proved very satisfactory to provide the desired seal and to permit the insertion and removal of fluids. However, from time to time, difficulty has been encountered with the stopper in that it is automatically ejected from the container breaking the sterility and causing contamination or loss of the contents.

It is the object of the present invention to provide an improved pierceable self sealing stopper of the above type which may be readily inserted in and removed from an opening in a container but which when inserted in the opening will remain firmly seated in place without danger of accidental release or ejection.

In accordance with the present invention such a stopper comprises a single integral body of resilient material and consisting of a tubular plug with a flange at one end forming an enlarged head and with a partition which extends across and closes the interior of the plug; the plug and partition defining at the head end of the plug a concave recess, which at its centre lies adjacent to the plane of the shoulder between the flange and plug, the surface of the partition remote from the flange being convex, and the plug being formed on its outer surface with an annular groove immediately adjacent the flange; the arrangement being such that when, in use, the stopper is pushed into the end of a container which has an internal diameter slightly less than the outer diameter of the tubular plug until the flange abuts the end of the container so that the plug and partition are compressed radially inwardly, the provision of the groove relieves stresses in the plug resulting from resistance of the flange to compression of the plug and the partition is deformed towards its convex surface to assist in resealing the partition after a hypodermic needle has been withdrawn through the partition.

One example of a blood collecting container fitted with a stopper constructed in accordance with the invention is illustrated in the accompanying drawings, in which:—

Figure 1 is a side elevation partially in section of the container and stopper;

Figure 2 is an enlarged detail view in central longitudinal section of the upper end of the container and stopper;

Figure 3 is an exploded view in perspective of the stopper and the upper portion of the container; and,

[*Price 4s. 6d.*]

Figure 4 is a partially sectional side elevation of the stopper.

The stopper 5 is shown in Figures 1 and 2 applied to the open upper end of a tubular container 6 which is closed at its lower end. This assembly is of the general type frequently used in collecting blood specimens and the stopper has sealing engagement with the container and the container is at least partially evacuated so that blood will be drawn into the container when a cannula having connection with a blood vessel is inserted through it.

The container 6 is preferably made of glass, but it may be made of a suitable plastic material inert to and unaffected by the blood or other fluid to be collected. Assembled with the container and stopper in Figure 1 is a holder 7 open at its lower end and of a size to have sliding fit with the container as shown. The holder 7 has a tapered top portion 8 formed with an aperture with which a hub-like fitting 9 has sealing engagement. A double ended cannula is mounted in sealing relationship with the fitting 9 with one end projecting into the holder and the other end projecting outwardly from it. In using the device illustrated in Figure 1, the outwardly projecting portion of the cannula may be inserted into a blood vessel and then the inwardly projecting portion of the cannula is projected through the stopper with the result that blood is drawn into the sealed, evacuated container 6. When the desired quantity of blood has been drawn into the container, the cannula, in normal practice, is withdrawn from the stopper and then from the blood vessel. Upon withdrawal of the cannula from the stopper, it automatically reseals itself. The container may be sterilized before use and may contain, for example, various blood treating and preserving materials.

The container as described illustrates one type of container to which the stopper may be applied and the assembly illustrated in Figure 1 represents one method of using the stopper for inserting or removing fluids from inside a container. It should be understood, however, that the stopper is applicable to any type of sealed container where it is desired to insert or remove fluids by means of a hypodermic needle.

The stopper 5 comprises a body portion made of a suitable resilient material inert to and unaffected by the fluids with which it is used. For most purposes, we find that natural or synthetic rubber serves quite satisfactorily. Various elastomeric plastic compositions having the above indicated characteristics may also be employed under certain circumstances as, for instance, the polymers and copolymers of vinylchloride or vinyldienechloride.

The body portion of the stopper comprises a plug 10 having a flange forming an enlarged head portion 12 integrally connected to its upper end. The outside diameter of the plug 10 is slightly larger than the inside diameter of the opening in the container with which it is intended to be used. Thus, when the plug is inserted into the open end of the container as shown in Figures 1 and 2, it is partially compressed. This helps to ensure sealing engagement with the container as well as self sealing of the stopper when a cannula which has been inserted through it is withdrawn. The diameter of the head portion should be large enough to overlap the open upper end of the container as shown in Figures 1 and 2 so that it can be pressed into engagement with it when the stopper is applied to the container. Recesses 14 and 16 are formed in the upper head end of the stopper and in the other end of the stopper respectively as shown. Extending across the stopper so as to overlap both the head and plug portions is a diaphragm 18 formed integrally with the remainder of the stopper. The diaphragm provides a partition or separation between the recesses 14 and 16 through which the cannula may be inserted when it is desired to add or remove fluid from the container. The upper surface of the diaphragm and the adjacent parts of the stopper define a smooth concave wall 20 of the recess 14 and the lower surface 22 of the diaphragm is smoothly convex. Thus, when the plug is compressed, the flow of the elastomeric material in the diaphragm is directed inwardly thereby minimizing stresses which might tend to eject or force the stopper outwardly from the container.

Around the outer surface of the plug, immediately adjacent the head 12, there is a circumferential groove 24 which serves to minimize or relieve the stresses adjacent this portion of the plug resulting from the resistance of the head of the stopper to compression of the plug when it is inserted in the opening in the container. Thus, stresses in this area of the plug which tend to eject the stopper from the container are minimized or eliminated. In order to facilitate the insertion of the plug end of the stopper into the opening of the container, the outer surface of the plug tapers inwardly towards its free end, as shown at 26.

In using the stopper, it is applied to a container having an opening whose inside diameter is slightly less than the outside diameter of the plug portion. The plug is inserted in the opening as shown in Figures 1 and 2 with the the flange overlapping and pressed against the outer end of the container. Thus, the stopper provides a seal for the open end of the container. The container may be evacuated by inserting a hypodermic needle through the diaphragm 18 and applying a vacuum to the needle or by inserting the stopper in the container while

in an evacuated chamber. When the needle is then withdrawn, the diaphragm is then self sealing. If the container is to be used for the collection of blood, blood drawing and preserving materials may be inserted therein. The sealed container may be sterilized in an autoclave in the usual manner. Liquids may be introduced into and withdrawn from the container by means of a hypodermic needle inserted through the diaphragm. In the collection of blood samples, the assembled container and stopper may be used with the holder 7.

When the stopper is assembled with the container in the manner illustrated and described, the plug 10 is partially compressed and the frictional engagement between the plug and container serves to hold the stopper in place against accidental displacement. Stresses and forces which might tend to eject the stopper from the container are relieved and minimized due to the provision of the circumferential groove 24 immediately adjacent to the head and due to the concavo-convex configuration of the diaphragm which directs the flow of elastomeric material inwardly when the plug is compressed. It will be seen that the stopper is designed so that the maximum amount of rubber is disposed down inside the tube or container to seal it firmly in place.

WHAT WE CLAIM IS:—

1. A self sealing pierceable stopper for sealing an open end of a tubular container, the stopper comprising a single integral body of resilient material and consisting of a tubular plug with a flange at one end forming an enlarged head and with a partition which extends across and closes the interior of the plug; the plug and partition defining at the head end of the plug a concave recess, which at its centre lies adjacent to the plane of the shoulder between the flange and plug, the surface of the partition remote from the flange being convex, and the plug being formed on its outer surface with an annular groove immediately adjacent the flange; the arrangement being such that when, in use, the stopper is pushed into the end of a container which has an internal diameter slightly less than the outer diameter of the tubular plug until the flange abuts the end of the container so that the plug and partition are compressed radially inwardly, the provision of the groove relieves stresses in the plug resulting from resistance of the flange to compression of the plug and the partition is deformed towards its convex surface to assist in resealing the partition after a hypodermic needle has been withdrawn through the partition.

2. A stopper according to claim 1, substantially as described with reference to the accompanying drawings.

3. A tubular container provided with a stopper according to claim 1 or claim 2, the outer diameter of the plug of the stopper being slightly greater than the inner diameter of one open end of the container.

4. A sealed container according to claim 3, substantially as described with reference to the accompanying drawings.

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984149 COMPLETE SPECIFICATION
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FIG. 1

FIG. 2

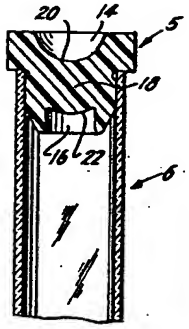

FIG. 3

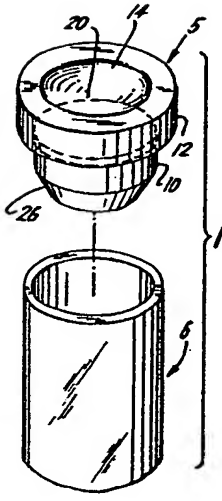

FIG. 4